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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,287	08/27/2003	Jack Saltiel	32001.UT	5496

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EXAMINER	
WONG, EDNA	

ART UNIT	PAPER NUMBER
1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,287	SALTIEL, JACK	
	Examiner	Art Unit	
	Edna Wong	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

The disclosure is objected to because of the following informalities:

page 1, line 2, the word "priority" should be amended to the word -- benefit --.

page 25, line 9, the "Brief Description" for FIG. 5 is missing.

page 25, line 13, "27)" should be amended to -- 27)) --.

page 28, line 1, the word "Sch m " should be amended to the word -- Scheme --.

page 31, the text is missing.

page 32, line 1, the word "Schem" should be amended to the word -- Scheme --.

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim **6** is objected to because of the following informalities:

Claim 6

line 1, a -- : -- (semicolon) should be inserted after the word "comprising".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims **6-9** are rejected under 35 U.S.C. 102(b) as being anticipated by **Stevens** (US Patent No. 4,686,023).

Stevens teaches a process for producing previtamin D (= previtamin D_3 or previtamin D_2), the process comprising:

irradiating a reaction mixture containing provitamin D (= 7-dehydrocholesterol or ergosterol) with light energy having a wavelength of approximately from 240 to 265 nm [col. 3, line 58 to col. 4, line 2; and cols. 5-6, Example 1] and with light energy having a wavelength of approximately from 300 to 330 nm (= in the 290-400 nm range) [col. 4, lines 32-49].

The first and second irradiations are sequential (col. 4, lines 32-49; and cols. 5-6, Example 1).

The reaction mixture further contains a solvent (col. 4, lines 50-53).

The reaction mixture further contains an organic solvent (col. 4, lines 50-53).

Since Stevens teaches all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

II. Claims **11, 13 and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by **Stevens** (US Patent No. 4,686,023).

Stevens teaches a process for producing previtamin D (= previtamin D_3 or previtamin D_2), the process comprising:

irradiating a reaction mixture containing tachysterol (col. 3, line 65 to col. 4, line 2) with light energy having a wavelength of approximately from 300 to 330 nm (= in the 290-400 nm range) [col. 4, lines 32-49].

The reaction mixture further contains a solvent (col. 4, lines 50-53).

The reaction mixture further contains an organic solvent (col. 4, lines 50-53).

Since Stevens teaches all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

III. Claims **24-28** are rejected under 35 U.S.C. 102(b) as being anticipated by **Stevens** (US Patent No. 4,686,023).

Stevens teaches a process for production of vitamin D (col. 1, lines 6-10), the process comprising:

(a) a first irradiation of a reaction mixture containing provitamin D (= 7-dehydrocholesterol or ergosterol) with light energy having a wavelength of approximately from 240 to 265 nm [col. 3, line 58 to col. 4, line 2; and cols. 5-6, Example 1];

(b) a second irradiation of the reaction mixture with light energy having a wavelength of approximately from 300 to 330 nm (= in the 290-400 nm range) [col. 4, lines 32-49]; and

(c) heating the reaction mixture after the second irradiation (= 50°-100°C) [col. 5, lines 57-62].

The heating consists of a temperature not exceeding 100°C (= 50°-100°C) [col. 5, lines 57-62].

The first and second irradiations are sequential (col. 4, lines 32-49; and cols. 5-6, Example 1).

The reaction mixture further contains a solvent (col. 4, lines 50-53).

The reaction mixture further contains an organic solvent (col. 4, lines 50-53).

Since Stevens teaches all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims **1-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

Stevens teaches a process for the production of previtamin D (= previtamin D_3 or previtamin D_2), the process comprising:

(a) a first irradiation of a reaction mixture containing provitamin D (= 7-dehydrocholesterol or ergosterol) with light energy having a wavelength of approximately 254 nm [col. 3, line 58 to col. 4, line 2; and cols. 5-6, Example 1]; and

(b) a second irradiation of the reaction mixture with light energy having a wavelength in the 290-400 nm range (col. 4, lines 32-49).

The first and second irradiations are sequential (col. 4, lines 32-49; and cols. 5-6, Example 1).

The reaction mixture further contains a solvent (col. 4, lines 50-53).

The reaction mixture further contains an organic solvent (col. 4, lines 50-53).

The method of Stevens differs from the instant invention because Stevens does not disclose wherein the light energy of the second irradiation has a wavelength of

approximately 313 nm.

Stevens teaches that the second stage is irradiated in the 290-400 nm range (col. 4, line 35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with wherein the light energy of the second irradiation has a wavelength of approximately 313 nm because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP 2144.05).

II. Claim **5** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 1-4 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Stevens is as applied above and incorporated herein.

The method of Stevens differs from the instant invention because Stevens does not disclose wherein the reaction mixture further contains methanol.

Like Stevens, Michishita teaches forming previtamin D (col. 14, lines 9-16). Michishita teaches that the reaction solvent includes ether solvents such as diethyl ether; alcohol solvents such as methanol; hydrocarbon solvents and halogenated hydrocarbon solvents (col. 14, lines 17-24).

The invention as a whole would have been obvious to one having ordinary skill in

the art at the time the invention was made to have modified the process described by Stevens with wherein the reaction mixture further contains methanol because methanol would have been functionally equivalent to use as the reaction solvent, in doing the same endeavor, as taught by Michishita (col. 14, lines 9-24).

III. Claim **10** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 6-9 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Stevens and Michishita are as applied above and incorporated herein.

IV. Claims **12, 16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 11, 13 and 14 above.

Stevens is as applied above and incorporated herein.

The method of Stevens differs from the instant invention because Stevens does not disclose the following:

a. Wherein said wavelength consist of approximately 313 nm, as recited in claim 12.

b. A method of estimating the progress of the process of Claim 11, the method comprising:

(i) determining ultraviolet absorption spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol;

(ii) monitoring the ultraviolet absorption spectrum for the reaction mixture; and

(iii) estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol, as recited in claim 16.

c. Wherein the ultraviolet spectra are measured using light energy having wavelengths from approximately 230 nm to approximately 340 nm, as recited in claim 17.

Regarding claim 12, Stevens teaches that the second stage is irradiated in the 290-400 nm range (col. 4, line 35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with wherein said wavelength consist of approximately 313 nm because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP § 2144.05).

Regarding claim 16, Stevens teaches that Dauben et al. reported that on the basis of the spectral data of the four major irradiation products, the yield of vitamin D analogues should be maximized by using a first step, irradiation with light of either 254

nm or 300 nm wavelength, and a second step irradiation with light of wavelength 330 nm or greater (col. 2, lines 61-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with a method of estimating the progress of the process of Claim 11, the method comprising:

(i) determining ultraviolet absorption spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol;

(ii) monitoring the ultraviolet absorption spectrum for the reaction mixture; and

(iii) estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol,

because the yield of vitamin D analogues would have been maximized as taught by Stevens (col. 2, lines 61-67).

Regarding claim 17, the invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with wherein the ultraviolet spectra are measured using light energy having wavelengths from approximately 230 nm to approximately 340 nm because the wavelength is a result-effective variable and one skilled in the art has the

skill to calculate the wavelength that would determine the success of the desired reaction to occur, absent evidence to the contrary. MPEP § 2141.03 and § 2144.05(b).

V. Claim **15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 11, 13 and 14 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Stevens and Michishita is as applied above and incorporated herein.

VI. Claims **18-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

Stevens is as applied above and incorporated herein.

Stevens also teaches a process for production of vitamin D (col. 1, lines 6-10), the process further comprising (c) heating the reaction mixture after the second irradiation (col. 5, lines 57-62).

The heating consists of a temperature not exceeding 100°C (= 50°-100°C) [col. 5, lines 57-62].

VII. Claim **23** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 18-22 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Stevens and Michishita is as applied above and incorporated herein.

VIII. Claim **29** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 24-28 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Stevens and Michishita is as applied above and incorporated herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edna Wong whose telephone number is (571) 272-1349. The examiner can normally be reached on Mon-Fri 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Edna Wong
Primary Examiner
Art Unit 1753

EW
August 31, 2005